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Attorneys for Plaintiff, Illumina, Inc.

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

ILLUMINA, INC.,

Case No. _____

Plaintiff,

COMPLAINT

vs.

JURY TRIAL DEMANDED

NATERA, INC.,

Defendant.

COMPLAINT

Plaintiff Illumina, Inc. (“Illumina”) for its complaint against Defendant Natera, Inc. (“Natera”) alleges as follows:

NATURE OF THE ACTION

1. This action arises under 28 U.S.C. §§ 1331 and the United States Patent Act, 35 U.S.C. § 100 *et seq.*

2. Plaintiff brings this action to halt Natera's infringement of its rights under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

PARTIES

1. Illumina is a corporation organized and existing under the laws of the State of Delaware, and is the owner of U.S. Patent No. 9,493,831 ("the '831 patent") (attached hereto as Exhibit 5).

2. Illumina is a leading developer, manufacturer, and marketer of life science tools and integrated systems for large-scale analysis of genetic variation and function. Illumina's products and services serve customers in a wide range of markets, enabling the adoption of genomic solutions in research and clinical settings. Illumina's customers include leading genomic research centers, academic institutions, government laboratories, and hospitals, as well as pharmaceutical, biotechnology, commercial molecular diagnostic laboratories, and consumer genomics companies. Illumina's portfolio of integrated sequencing and microarray systems, consumables, and analysis tools is designed to accelerate and simplify genetic analysis. Most recently, Illumina achieved a significant milestone in medical progress through the launch of sequencing technology capable of pushing the cost of sequencing the human genome down below to \$1000.

3. On information and belief, Natera is a company organized and existing under the laws of Delaware, with its principal place of business at 201 Industrial Rd, San Carlos, CA 94070. Natera provides a non-invasive diagnostic test for the determination of fetal chromosomal abnormalities that it markets under the trademark “Panorama™ Natera Prenatal Screen.” On information belief, Natera performs the Panorama™ Natera Prenatal Screen at its facility in San Carlos, California.

JURISDICTION AND VENUE

4. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 et seq. This Court has federal question jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1338(a) because this is a civil action arising under the Patent Act.

5. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) because a substantial part of the events giving rise to Illumina's claim occurred in this District and because Defendants are subject to personal jurisdiction in this District. Indeed, upon information and belief, Natera's principal place of business is in this District in San Carlos, California. This Court also has jurisdiction over Natera because, upon information and belief, Natera, directly or indirectly, uses,

1 offers for sale, and/or sells the Panorama™ Natera Prenatal Screen throughout the United States and in
2 this judicial district.

3 **BACKGROUND**

4 6. Plaintiff repeats and re-alleges the foregoing paragraphs as if set forth specifically
5 herein.

6 7. In or around February 2013, Natera began selling and offering to sell its commercial
7 non-invasive prenatal test for Down syndrome, which it refers to by the trade name “Panorama™
8 Natera Prenatal Screen”.

9 8. Technical literature describing the technology underlying the Panorama™ Natera
10 Prenatal Screen explains that it involves *inter alia* analysis of cell-free DNA present in maternal blood
11 using multiplex targeted PCR. *See, e.g.,* Hall, M., Hill, M., Zimmerman, B., Sigurjonsson, S.,
12 Westemeyer, M., Saucuer, J., Demko, Z., and Rabinowitz, M., Non-invasive Prenatal Detection of
13 Trisomy 13 Using a Single Nucleotide Polymorphism- and Informatics-Based Approach, *PLOS One*.
14 (2014) (attached hereto as Exhibit 2).

15 9. When Natera performs the Panorama™ Natera Prenatal Screen, it infringes literally or
16 under the doctrine of equivalents at least claims 1-3, 6-10, 13-22, and 24 of the '831 patent. For
17 instance, representative claim 1 of the '831 patent is listed below:

18 1. A method for preparing a sequencing library from a maternal blood sample, the
19 method comprising:

20 a. obtaining a maternal blood sample comprising fetal and maternal cell-
21 free DNA;

22 b. selectively enriching a plurality of non-random polynucleotide sequences
23 of genomic DNA from said fetal and maternal cell-free DNA to generate a
24 library of enriched non-random polynucleotide sequences, wherein said plurality
25 of non-random polynucleotide sequences comprises at least 100 different non-
26 random polynucleotide sequences selected from a chromosome tested for being
27 aneuploid, said enriching comprising:
28

(i) a first amplification step to generate a plurality of first reaction
products, said amplification comprising at least 100 first primers
configured to amplify at least 100 different non-random polynucleotide
sequences;

(ii) a second amplification step to generate a second reaction product,
said amplification comprising a second set of primers comprising
sequences contained in the first reaction products; and

(iii) a third amplification step to generate a third reaction product comprising said library of enriched non-random polynucleotide sequences, said amplification comprising a third set of primers comprising sequences contained in the second reaction products;

wherein at least one primer of at least one of the second and third sets of primers includes a sequence configured to be added to the different non-random polynucleotide sequences to permit the enriched non-random polynucleotide sequences of the library to anneal to a same sequencing primer for the enriched non-random polynucleotide sequences of the library.

6 10. As set forth in the scientific literature regarding the Panorama™ Natera Prenatal Screen,
7 Panorama includes a nested PCR process in which three rounds of PCR are used to amplify 19,488
8 non-random single nucleotide polymorphism-containing genetic loci in a maternal blood sample
9 comprising fetal and maternal cell-free DNA. *See, e.g.*, Exhibit 2 at 2. During the third round of PCR,
10 a barcoded tag is introduced to the amplified genetic loci to identify the sample from which it came.
11 *Id.* Upon information and belief, Natera carries out this process when it performs the Panorama™
12 Natera Prenatal Screen at its San Carlos facility.

13 11. As an example, attached hereto as Exhibit 6 is a preliminary and exemplary claim charts
14 detailing Natera's infringement of at least claims 1-3, 6-10, 13-22, and 24 of the '831 patent. This
15 chart is not intended to limit Plaintiffs' right to modify it or any other claim chart or allege that other
16 activities of Natera infringe the identified claims or any other claims of the '831 patent or any other
17 patents. Exhibit 6 is hereby incorporated by reference in its entirety. Each claim element in Exhibit 6
18 that is mapped to the Panorama™ Natera Prenatal Screen shall be considered an allegation within the
19 meaning of the Federal Rules of Civil Procedure and therefore a response to each claim element is
20 required.

21 12. On information and belief, Natera has long since been aware of the '831 patent and the
22 fact that performance of the Panorama™ Natera Prenatal Screen constitutes infringement of the '831
23 patent. For instance, by way of a December 20, 2016 letter, Illumina expressly informed Natera of the
24 existence of the '831 patent and the fact that performance of the Panorama™ Natera Prenatal Screen
25 leads to infringement.

26 13. Furthermore, as of late 2016, Illumina was in negotiations regarding the '831 patent
27 with ARUP Laboratories, which provides a test that performs and operates substantially similarly to
28 the Panorama™ Natera Prenatal Screen and was developed in consultation with Natera. *See Exhibit 7.*

1 As a result of these negotiations, ARUP Laboratories agreed to license the '831 patent along with a
2 suite of other patents related to non-invasive prenatal testing that is controlled by Illumina. On
3 information and belief, Natera was aware that ARUP Laboratories' had been in negotiations with
4 Illumina regarding the '831 patent. By virtue of these negotiations, Natera had full awareness of the
5 '831 patent and the fact that performance of the Panorama™ Natera Prenatal Screen leads to
6 infringement.

7 **COUNT I**

8 14. Plaintiff repeats and re-alleges the foregoing paragraphs as if set forth specifically
9 herein.

10 15. On November 15, 2016, the United States Patent and Trademark Office duly and legally
11 issued the '831 patent, entitled "Methods of Fetal Abnormality Detection" which is assigned to
12 Plaintiff.

13 16. On information and belief, Natera has infringed and continues to infringe at least claims
14 1-3, 6-10, 13-22, and 24 of the '831 patent pursuant to 35 U.S.C. § 271(a), literally or under the
15 doctrine of equivalents, by performing within the United States without authority the Harmony™
16 Prenatal test. As an example, attached as Exhibit 6 is a preliminary and exemplary claim chart
17 detailing Natera's infringement of these claims of the '831 patent. This chart is not intended to limit
18 Plaintiff's right to modify the chart or allege that other activities of Natera infringe the identified
19 claims or any other claims of the '831 patent or any other patents.

20 17. Exhibit 6 is hereby incorporated by reference in its entirety. Each claim element in
21 Exhibit 6 that is mapped to Natera's Panorama™ Natera Prenatal Screen shall be considered an
22 allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each
23 claim element is required.

24 18. On information and belief, Natera's infringement has been willful and deliberate since,
25 at least December 20, 2016, the date Illumina expressly informed Natera of the '831 patent and the fact
26 that performance of the Panorama™ Natera Prenatal Screen leads to infringement.

27 **JURY DEMAND**

28 19. Plaintiff demands a jury trial on all issues so triable.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

A. A judgment that Natera has infringed the '831 patent and that the '831 patent is valid;

B. Damages or other monetary relief, including, but not limited to, costs and pre-and post-judgment interest, to Plaintiff;

C. A declaration that Natera's infringement was willful and deliberate, and an increase to the award of damages of three times the amount found or assessed by the Court, in accordance with 35 U.S.C. § 284;

D. An order enjoining Natera and its officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert therewith from further infringement of the '831 patent;

E. Such further and other relief as this Court deems proper and just, including, but not limited to, a determination that this is an exceptional case under 35 U.S.C. § 285 and an award of attorneys' fees and costs to Plaintiff in this action.

1 DATED: March 16, 2018

Respectfully submitted,

2 /s/ Edward R. Reines _____

3 Edward R. Reines

4 Derek Walter

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